

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
LUFKIN DIVISION

IOVATE HEALTH SCIENCES, INC.,	§	
UNIVERSITY OF FLORIDA RESEARCH	§	
FOUNDATION, INC. and FLAMMA SPA.,	§	
	§	Civil Action No. 9:07-CV-46
<i>Plaintiffs,</i>	§	
	§	
v.	§	JUDGE RON CLARK
	§	
BIO-ENGINEERED SUPPLEMENTS &	§	
NUTRITION, INC., d/b/a BSN Inc. and	§	
MEDICAL RESEARCH INSTITUTE, .	§	
	§	
<i>Defendants.</i>	§	

**MEMORANDUM OPINION AND ORDER CONSTRUING CLAIM TERMS OF
UNITED STATES PATENT NOS. 5,973,199 and 6,100,287 (PART I)**

Plaintiffs Iovate Health Sciences, Inc. and University of Florida Research Foundation, Inc.¹ filed suit against Defendants Bio-Engineered Supplements & Nutrition, Inc., d/b/a BSN Inc., and Medical Research Institute, claiming infringement of U.S. Patent Nos. 5,973,199 (“the ‘199 patent”) and 6,100,287 (“the ‘287 patent”). The court conducted a *Markman* hearing to assist the court in interpreting the meaning of the disputed claim terms. Having carefully considered the patents, the prosecution history, the parties’ briefs, and the arguments of counsel, the court now makes the following findings and construes the disputed claim terms in the ‘199 patent as follows.²

¹A third Plaintiff, Flamma SpA was dismissed from the suit on October 4, 2007, after it sold all of its rights, title, and interest in the ‘199 patent to Iovate. *See* Doc. # 56.

²The transcript of the hearing contains a number of representations and agreements of the parties and their answers to technical questions from the court, all of which will not be repeated here, but which assisted the court in reaching the conclusions set out in this Order. This Order governs in the event of any conflict between the Order and the court’s preliminary analysis at the

I. CLAIM CONSTRUCTION STANDARD OF REVIEW

Claim construction is a matter of law. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 116 S. Ct. 1384 (1996) (“*Markman II*”). “The duty of the trial judge is to determine the meaning of the claims at issue, and to instruct the jury accordingly.” *Exxon Chem. Patents, Inc. v. Lubrizoil Corp.*, 64 F.3d 1553, 1555 (Fed. Cir. 1995) (citations omitted), *cert. denied*, 518 U.S. 1020, 116 S.Ct. 2554 (1996).

“‘[T]he claims of the patent define the invention to which the patentee is entitled the right to exclude.’” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005)(*en banc*)(citation omitted), *cert. denied*, 546 U.S. 1170, 126 S.Ct. 1332 (2006). “Because the patentee is required to ‘define precisely what his invention is,’ it is ‘unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms.’” *Phillips*, 415 F.3d at 1312 (quoting *White v. Dunbar*, 119 U.S. 47, 52 (1886)).

The words of a claim are generally given their ordinary and customary meaning. *Phillips* 415 F.3d at 1312. The “ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.” *Id.* at 1313. Analyzing “how a person of ordinary skill in the art understands a claim term” is the starting point of a proper claim construction. *Id.*

A “person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.” *Phillips*, 415 F.3d at 1313. Where a claim term has a particular meaning in the field of art, the court must examine those sources available to the public to show

hearing. The transcript will be cited as Tr. p. __, ll. __.

what a person skilled in the art would have understood the disputed claim language to mean. *Id.* at 1414. Those sources “include ‘words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.’” *Id.* (citation omitted).

“[T]he ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.” *Id.* at 1314. In these instances, a general purpose dictionary may be helpful. *Id.*

The Federal Circuit has emphasized the importance of the specification. “[T]he specification ‘is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term.’” *Phillips*, 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). A court is authorized to review extrinsic evidence, such as dictionaries, inventor testimony, and learned treatises. *Phillips*, 415 F.3d at 1317. Their use should be limited to edification purposes. *Id.* at 1319.

The intrinsic evidence, that is, the patent specification, and, if in evidence, the prosecution history, may clarify whether the patentee clearly intended a meaning different from the ordinary meaning, or clearly disavowed the ordinary meaning in favor of some special meaning. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979-80 (Fed. Cir. 1995); *aff’d*, 517 U.S. 370, 116 S.Ct. 1384 (1996). Claim terms take on their ordinary and accustomed meanings unless the patentee demonstrated “clear intent” to deviate from the ordinary and accustomed meaning of a claim term by redefining the term in the patent specification. *Johnson Worldwide Assoc., Inc. v. Zebco Corp.*, 175 F.3d 985, 990 (Fed. Cir. 1999).

The “‘ordinary meaning’ of a claim term is its meaning to the ordinary artisan after reading the entire patent.” *Phillips*, 415 F.3d at 1321. However, the patentee may deviate from the plain and ordinary meaning by characterizing the invention in the prosecution history using words or expressions of manifest exclusion or restriction, representing a “clear disavowal” of claim scope. *Teleflex, Inc. v. Ficoso N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002). It is clear that if the patentee clearly intended to be its own lexicographer, the “inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316.

II. PATENT BACKGROUND AND TECHNOLOGY

A. The ‘199 Patent

The ‘199 patent is directed to the water soluble organic salts of creatine. These creatine salts have the advantage of dissolving more readily in water and being more stable than the forms of creatine found in the prior art. Creatine is a sarcosine derivative (i.e., an N-methyl derivative of the amino acid glycine) found in muscle tissue that is used to supply muscles with energy. Creatine supplements are often used by athletes to build muscle mass or enhance performance.

B. The ‘287 Patent

The ‘287 patent is directed to compositions and methods for enhancing muscle performance and recovery from fatigue in both humans and animals. The composition contains a ketoacid and an amino acid, where the amino acid is cationic (positively charged) or dibasic (containing two basic groups).

C. One of Ordinary Skill in the Art

Iovate suggests that a person of ordinary skill with respect to the ‘287 patent “would be familiar with nutritional supplementation and with the basic teachings of biochemistry and

physiology or exercise science, as well as with the chemistry of the amino acids and ketoacids in the claimed compositions.” Pl. Cl. Const. Br. at p. 8 [Doc. #86]. Without suggesting a specific definition for the person of ordinary skill on the ’199 patent, Iovate states that the pertinent knowledge (familiarity with organic chemistry) is not in dispute. Pl. Reply Br. at p.1 [Doc. #113]

MRI argues that a person of ordinary skill in the art with respect to the ’199 patent is two years of college-level chemistry, including at least one year of organic chemistry. Def. MRI Cl. Const. Br. at pp. 1-2 [Doc. # 100]. For the ’287 patent, MRI suggests that it covers the fields of nutrition, biology, and chemistry. The person of ordinary skill with respect to this patent would have three years of collegiate or graduate study of chemistry, including one year of organic chemistry and one year of biochemistry. *Id.* at p. 2. BSN does not provide a definition of the person of ordinary skill in the art for either patent.

Based on the patents and their cited references, the tutorials, and the representations of the parties and their experts, the court finds that “one of ordinary skill in the art” covered by the ’199 patent is someone with the equivalent of a “four year” degree from an accredited institution (usually denoted in this country as a B.S. degree) with a concentration of courses in chemistry, including at least two semesters of organic chemistry, as well as a minimum of one year of experience in a related field, such as working in a chemistry or biochemistry lab as a researcher, teacher, or the like. Additional graduate education might substitute for experience, while significant experience in the field of chemistry might substitute for formal education. After reviewing it at the hearing, the parties agreed to this definition. Tr. at p. 9, l. 13- p. 10, l. 4.

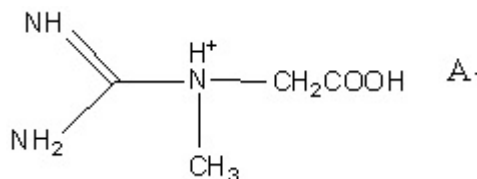
The court further finds that “one of ordinary skill in the art” covered by the ’287 patent is someone with the equivalent of a four year degree from an accredited institution with a

concentration of courses in chemistry (including at least two semesters of organic chemistry and two semesters of biochemistry), biology, biochemistry, physiology, and nutrition, as well as a minimum of one year of experience in a related field involving nutrition and physiology, nutritional supplements, exercise science, or the like. Additional graduate education might substitute for experience, while significant experience in a related field might substitute for formal education. After reviewing it at the hearing, the parties had no substantive objections to this definition. Tr. at p. 11, ll. 9-13; p. 13, ll. 10-12; p. 15, l. 4.

III. DISPUTED TERMS IN THE '199 PATENT

The parties dispute the entire meaning of claim 1, which reads as follows:

An isolated hydrosoluble salt of creatine of the formula:



wherein A- represents the anion of citric, maleic, fumaric, or malic acid.

The parties agreed that “hydrosoluble” means “water soluble.” Tr. at p. 15, ll. 15-24. The parties also agree that the claim generally discloses only four different combinations of creatine and anion: (1) creatine and citric acid; (2) creatine and maleic acid; (3) creatine and fumaric acid; and (4) creatine and malic acid. Tr. at p. 16, ll. 5-18; p. 19, l. 2- p. 20, l. 2. The first dispute is over the meaning of “isolated.”

A. The Meaning of “Isolated”

Iovate’s suggestion that “isolated” merely means “separated from solution” is not completely satisfactory. Iovate’s expert, Dr. Gokel, pointed to a supporting definition from a

dictionary with a copyright renewal date of 1972, and explained that the specification described a two- step process involving separation from solution followed by purification. Tr. at p. 30, l. 16 - p. 31, l. 9. "Separation" may be a generic definition in some dictionaries, but the claim uses the word "isolated" to describe the final product, the "hydrosoluble salt of creatine." In this context, "isolated" cannot refer merely to an initial step in the process of preparing the salt.

BSN argues that "isolated" means "in a pure condition from all other substances." In MRI's proposal, "isolated" means "an uncombined or pure water soluble salt of creatine." With respect to MRI's construction, MRI agreed that "uncombined" has no special meaning in chemistry in the context of this claim; rather, it was just a "different way of saying pure." Tr. p. 21, ll. 15-23.

BSN and MRI also agreed that they were not arguing that the use of "isolated" in the claim prohibited the packaging of the salt of creatine with other ingredients for sale. Tr. p. 22, l. 14- p. 23, l. 4.

Using "pure" in a definition to the jury raises an obvious question - how pure is "pure"? The specification states that the salts are prepared by concentrating and filtering the solution. '199 patent, col. 1, l. 53 - col. 2, l. 3. One skilled in the art would know that even with modern techniques, this would not result in a product that was "100% pure." For example, repeated distillations of a solution, or repeated filtration with finer filters could increase purity. Defendants' experts agreed with this analysis, opining that "pure" would include a range from 95% to 99% purity, and admitted that a chemist could choose methods that would determine the degree of purity. Tr. p. 26, l. 4 - p. 28, l. 12; p. 28, l. 23 - 30, l. 3.

The main problem with Defendants' position is the lack of support in the patent specification, claims, and prosecution history. The specification describes examples of "99.2%

titer” and “99.8% titer,” but this usage of “titer” has no standard meaning. ’199 patent, col. 2, ll. 32, 39. Both Dr. Gokel and Dr. Woolf candidly admitted they could provide no supporting reference that would indicate a known definition of this use of the word. Tr. at p. 44, ll. 16-24. Dr. Buynak gave an unsubstantiated opinion that “titer” was used in a way that supported his position, but admitted that he had not looked the word up prior to the hearing. Tr. at p. 44, ll. 1-11; ll. 21-22. Neither the court nor its technical advisor could find a reference using “titer” in relation to a method of denoting a degree of purity. Tr. at p. 44, l. 25- p. 45, l. 6.

BSN argued that during prosecution, the applicant stated that the invention “provides the only process of preparation of an organic homogenous and balanced salt, able to immediately release the creatine necessary to obtain the desired concentration of pure creatine, that is, free from creatinine.” Amendment of 7/31/98, Def. BSN’s Cl. Const. Br., Ex C, at p. 5 [Doc. # 101]. The applicant goes on to say that this result is obtained “thanks to the particular process of preparation of the salt, which is carried out....in order to prevent creatine from undergoing isomerization...” *Id.* BSN suggests that this means that the applicant intended “isolated” to mean “pure creatine, which is free from creatinine.” However, the applicant’s reference to a process that will “release the creatine necessary” is a description about what happens to the salt when it is used, not how it is produced. This reference does not justify a conclusion that “isolated” is used synonymously with “in a pure condition from all other substances.”

Iovate pointed to Examples 1 and 2 in the specification, which refer to “obtaining 90% of salts” and “obtaining 87% of salt,” respectively. ’199 patent, col. 2, ll. 31-32 and 40. However it is not clear if this refers to a level of purity, or a percentage derived by comparing the amount of creatine in the final salt preparation with the creatine originally placed in solution.

The court is construing a patent, not an Ivory soap commercial. Resolution of this case will not be aided by a definition that permits experts to quibble before the jury over “degrees of purity” that are not disclosed in the specification. *See* Tr. at p. 25, l. 19 - p. 29, l. 10. Additionally, the prosecution history strongly indicates that the patent does not disclose, and the claims do not teach, some level of “purity.”

The Examiner initially rejected claim 1 of what later issued as the '199 patent as obvious over, among others, U.S. Patent No. 5,091,171 (“the Yu reference”). Yu taught compositions of an amphoteric compound (which could be creatine) with hydroxyacids (including citric and malic acid), where the product of the hydroxyacids and amphoteric compound did not have to be isolated. 5/27/98 Office Action, Def. BSN Cl. Const. Br., Ex. B, at p. 3 [Doc. # 101]. The applicant subsequently amended claim 1 to substitute “an isolated hydrosoluble salt” for the more generic “salts.” 7/31/98 Response to Office Action, Def. BSN Cl. Const. Br., Ex. C, at p. 2. The Examiner again rejected claim 1 over U.S. Patent No. 5,627,172 (“the Almada reference”), stating: “As to the purity of the prior art compound or the presence of creatinine, *this is of no moment*. The instant claims *do not have any requirement as to purity or the presence of creatinine*.” 11/12/98 Final Office Action, Def. BSN Cl. Const. Br., Ex. D, at p. 2 (emphasis added).

Given this clear statement by the Examiner, it would be a strained construction to define “isolated” based upon some particular level of purity or the absence of creatinine. The court therefore construes this term as follows:

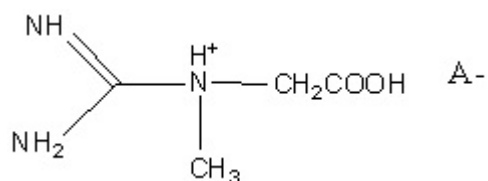
“Isolated,” as used in this claim, means that creatine and one of the four acids have been processed to the point that the salt of creatine is present in a concentration chosen by the person preparing the salt.

B. Construction of the Structural Formula

Iovate suggests that the remainder of the term should be construed as: “creatine salt, that is water soluble, formed between creatine and citric acid, creatine and maleic acid, creatine and fumaric acid, or creatine and malic acid.”

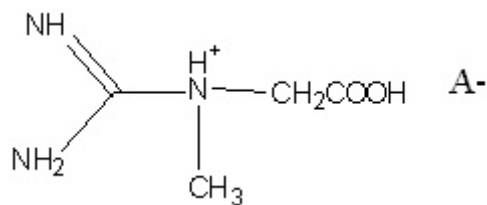
BSN argues that the remainder of the term should be construed as:

a water soluble salt of creatine of the structural formula:



[specifically, the type depicted in the above formula in which the proton (i.e., the hydrogen cation) is placed on the central nitrogen of the creatine molecule (i.e., the nitrogen attached to the methyl group)] in a pure condition from all other substances and consisting of one of the four compounds creatine citrate, creatine maleate, creatine fumarate, or creatine malate where the creatine is present in a 1:1 ratio to the anion of citric, maleic, fumaric, or malic acid.

MRI proposes that the remainder of the term should be construed as: “of the formula:

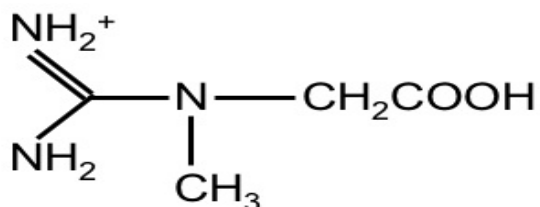


wherein the salt of creatine is limited to mon creatine salts of citric acid, maleic acid, fumaric acid, or malic acid.”

In short, the Defendants want the claim limited to the mon creatine form of the salt where a single creatine molecule binds with a single molecule of one of the four acids. BSN seems to

want an even more restrictive construction limiting the monocreteine to the exact form shown in their proposed definition. In essence, BSN argues that the formula should be specifically described in words, because this is an “atypical” creatine molecule. According to BSN, in the typical creatine molecule, the proton is placed on the terminal nitrogen atom (i.e., on the C=N nitrogen atom), while in the structure disclosed in the '199 patent, it is placed on the central nitrogen atom (i.e., on the H-N nitrogen atom). Adding a proton to the central nitrogen atom would affect the resonance stabilization: rather than having sp^2 orbital hybridization (which would allow the central nitrogen atom to participate in a stabilizing resonance interaction), it has an sp^3 hybridization (which would prevent such participation). As a result, a person of ordinary skill in the art would understand that claim 1 designates an atypical protonation state.

This argument was not grounded in the specification, but rather on Dr. Buynak's somewhat creative analysis that the chemical formula shown in the specification represents the exact structure of a molecule which does not move or change, and in which, perhaps, even the electrons do not move. Tr. at p. 57, ll. 13- 20; p. 60, l. 13 - p. 62, l. 25; p. 65, ll. 3-8. Dr. Buynak explained his statements, in part, by opining that the proton (\oplus) attached to the central nitrogen atom in the structure depicted in claim 1 should have been shown as attached to the HN with the double bond, at the upper left of the drawing, as shown below. Tr. p. 62, l. 3 - p. 64, l. 13.



However Dr. Buynak admitted that one of ordinary skill would know where the proton (\oplus) should actually be. Tr. p. 63, ll. 1-4. Quibbling over something that one of skill in the art would recognize as an error, if indeed it is one, and know what was actually intended does not add to the claim construction.

As noted above, Iovate agrees that the creatine salt is combined with one of the four enumerated acids, but asserts that since a person of ordinary skill in the art would understand that some of these acids have more than one negative charge, the patent teaches di-and tri-creatine salts, in addition to the monocreatine form.

Certainly, the '199 patent could have been written more clearly, and the services of a proof-reader would not have been amiss. However, Congress has decided that a patent is presumed valid. 35 U.S.C. § 282; *see also Adenta GmbH v. OrthoArm, Inc.*, 501 F.3d 1364, 1371 (Fed. Cir. 2007). Mere difficulty in construction is not a reason for the court to unduly restrict the claim.

To one skilled in the art, an “anion” is a negatively charged ion, a definition which has been consistent over time. *See, e.g., Academic Press Dictionary of Science and Technology* 118 (1992)(“a negatively charged ion”); Thomas M. Devlin, *Textbook of Biochemistry* 5 (4th ed. 1997)(a cation is a “positively charged ion” and an anion is a “negatively charged ion”) *McGraw-Hill Dictionary of Scientific and Technical Terms* 104 (6th ed. 2003)(“an ion that is negatively charged”). While Dr. Buynak stated that “anion” can only mean an ion with one negative charge, Defendants are unable to support that construction with any dictionary, text, or other reference. While dictionaries and textbooks are extrinsic evidence, their unbiased assertions are more likely to be reliable than the unsubstantiated conclusions of an expert testifying on behalf of a party.

BSN argues that the structural formula of the claim itself imposes limitation of a one-to-one (1:1) ratio of creatine to acid. However, neither the claim nor the specification states such a limitation. BSN asserts that the lack of brackets around the formula with an “n” or other subscript means that the inventor must have intended to limit the invention to monocreatine salts. According to BSN, this is further supported by the fact that the anion (A^-) in the formula has only a single negative charge; if the claim was intended to encompass di- or tri-creatine salts, the anion would have to be designated “ A^{-2} ” or “ A^{-3} ”.

The claim must be read in light of the specification, from the point of view of one of ordinary skill in the art. The specification begins by drawing the same formula depicted in claim 1, and stating that “ A^- represents the anion of a mono, bi- or tricarboxylic acid. Preferred anions are the citrate, maleate, fumarate, tartrate or malate.” ‘199 patent, col. 1, ll. 13-15 (emphasis added). The patentee is entitled to be his own lexicographer, so long as he clearly expresses his intent to do so in the specification. *Merck & Co. v. Teva Pharms., USA, Inc.*, 395 F.3d 1364, 1370 (Fed. Cir. 2005).

One skilled in the art would know that since they are bi- or tri-carboxylic acids, some of the four acids listed in the claim have ionic forms with two or three negative charges.³ *See, e.g.*, Def. BSN Tech. Synopsis at p. 2 (“A citrate is an ionic form of citric acid...that is, citric acid minus three hydrogen ions.”) [Doc. # 90].⁴ One of skill would also know that, in solution, the ionic

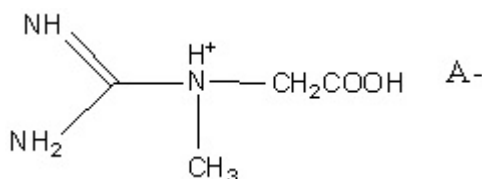
³In the discussion with counsel and their experts the court focused on citric acid because all agreed it was common and that one of ordinary skill would be familiar with its three ionic forms. Tr. at p. 70, l. 8 - p. 71, l. 8.

⁴At the end of its technology synopsis, supposedly submitted for the purpose of educating the court, BSN stated “Nothing herein should be construed as an admission by BSN.” *See* Doc. # 90 at 11. Questioning revealed that BSN had copied excerpts from Wikipedia, an on-line

form of one of these acids would be affected by the pH of the solution. These ionic forms would allow two or three molecules of creatine to attach, thus creating the di- and tri-creatine forms, respectively.

The court construes this term as follows:

“An isolated hydrosoluble salt of creatine of the formula:



wherein A- represents the anion of citric, maleic, fumaric, or malic acid” means:

“an isolated (as defined by the court) water soluble salt formed by the combination of creatine with one of the ionic (negatively charged) forms of citric acid, maleic acid, fumaric acid, or malic acid.”

“Salt” is what is formed when a base (molecules that have a positive charge when dissolved in water) is combined with an acid (molecules that have a negative charge when dissolved in water).

“Ionic (negatively charged) forms” refers to the fact that some acids, like citric acid, can have different forms with one, two, or three negative charges per molecule, depending on the solution conditions.

encyclopedia service that can be altered at will by any user. Tr. at p. 109, l. 16 - p. 110, l. 25. In spite of BSN’s kind warning to the court that the documents and statements it presents to the court are not to be trusted, BSN’s description of citric acid in three ionic forms is, in this instance, correct.

IV. CONCLUSION

The jury shall be instructed in accordance with the court's interpretation of the disputed claim terms in the '199 patent.

So **ORDERED** and **SIGNED** this **28** day of **March, 2008**.

A handwritten signature in black ink, appearing to read "Ron Clark", written in a cursive style.

Ron Clark, United States District Judge